

REMARKS

In the Claims

Applicant amended claim 11 to clarify the step of “providing a flow resistance ... such as to maintain a dynamic positive pressure” The limitation now reads “providing a flow resistance to the gas flow exiting the other nostril of the subject such as to maintain a dynamic positive pressure in the nasal airway of the subject, wherein the gas flow, while under resistance, continues exiting the other nostril.”

Claim Rejections – 35 USC § 102

Claims 5, 6, 8, 52, 55, 58-60, 63-66, 75, and 76 stand rejected under 35 USC § 102(b) as allegedly being anticipated by U.S. Patent 746,749 to Seidel (“Seidel”). Applicant respectfully disagrees.

Seidel does not anticipate independent claim 5 for the principal reason that Seidel does not disclose a method comprising the step of “sealing one of the nostrils of a subject to an outlet of a delivery unit such as to prevent the escape of a gas flow through the one nostril.” The Office, in remarks attached to the May 3, 2010 Advisory Action, alleges that “a seal is formed when end D [of the Seidel device] is inserted into the nostril.” However, Fig. 1 of Seidel demonstrates that the Office’s allegation is unfounded. Fig. 1 illustrates the device in use in a human subject. A close inspection of Fig. 1 reveals open space between the outer circumference of the Seidel nosepiece and the inner circumference of the subject’s nostril. Accordingly, Fig. 1 does not disclose Applicant’s sealing step. Furthermore, there is no description of a sealing step throughout the remainder of the Seidel document.

The foregoing claims were all essentially the subject of previous 102(b) rejections based on Seidel, which Applicant overcame to the Office’s satisfaction in a previous response. Namely, in the Office Action mailed October 2, 2006, claims 1-3, 5, 6, 21-23, and 26-29 were rejected under 35 USC § 102(b) based on Seidel.¹ In response, Applicant

¹ See the October 2, 2006 Office Action at pages 4-6.

demonstrated that Seidel does not anticipate any of the subject claims.² In the next Office Action, the Office stated that “Applicant’s arguments ... with respect to Seidel were fully considered and are persuasive.”³ Accordingly, the Office withdrew the § 102(b) rejections over Seidel.

Based on this record, Applicant is very surprised to see the Office resurrect essentially the same Seidel rejections for essentially the same reasons previously overcome by Applicant. Applicant maintains that the pending claims are patentable over Seidel and incorporates by reference herein the arguments concerning Seidel made in Applicant’s March 30, 2007 Response. Current independent claim 5 corresponds to claim 5 as pending on March 30, 2007, having only been rewritten in independent form. Claims 6, 8, 52, 55, 58-60, 63-66, 75, and 76 are allowable as depending upon allowable independent claim 5.

Claim Rejections – 35 USC § 103

Seidel

Independent claim 11 and dependent claims 67-74 stand rejected under 35 USC § 103(a) as allegedly being unpatentable over Seidel. Applicant respectfully disagrees.

The sole rationale provided by the Office for the rejection of claim 11 as being obvious over Seidel is that, allegedly, “it is well known in the art of nasal inhalers to plug a nostril not receiving treatment when using a nasal treatment requiring only one nostril.”⁴ Presumably, this assertion is directed to the limitation of claim 11 in which the method is described as “providing a flow resistance to the gas flow exiting the other nostril of the subject such as to maintain a dynamic positive pressure in the nasal airway of the subject.”

The Office’s position as to claim 11 fails for at least two reasons. First, the provided rationale fails to establish a *prima facie* case of obviousness because it is a mere conclusory statement that lacks a clear rational underpinning supporting a legal

² See the March 30, 2007 Response at pages 14-16.

³ See the June 12, 2007 Office Action at page 2.

⁴ See the January 22, 2010 Office Action at page 3.

conclusion of obviousness. *See* MPEP 2142.

Secondly, the Office's rationale, even if substantiated by more than a mere conclusory statement, does not apply to the subject matter of claim 11. The plugging of a nostril not receiving treatment is antithetical to the element of claim 11 in which there is recited the provision of "a flow resistance to the gas flow *exiting* the other nostril of the subject such as to maintain a *dynamic* positive pressure in the nasal airway of the subject." In order to clarify the meaning of "*dynamic*" positive pressure, Applicant has amended claim 11 to further provide that "*the gas flow, while under resistance, continues exiting the other nostril.*" In contrast to a static pressure, claim 11 requires the maintenance of a dynamic pressure in that the gas continues to flow out of the other nostril even when subjected to resistance. If a plug were placed in the second nostril, it would prevent gas from continuing to exit the nostril while under resistance and would prevent the maintenance of a dynamic positive pressure in the nasal airway of the subject.

Applicant respectfully submits that the differences between amended claim 11 and Seidel would not have been obvious to one of ordinary skill in the art. As discussed above, Applicant maintains the arguments concerning Seidel from the March 30, 2007 Response, and incorporates them herein by reference in their entirety. Currently amended claim 11 includes all of the limitation of claim 11 as pending on March 30, 2007. Therefore, Applicant respectfully submits that currently pending claim 11 is not disclosed or suggested by Seidel.

Furthermore, dependent claims 67-74 are allowable as depending upon allowable base claim 11.

Harding

Independent claims 11, 40 and 41, and dependent claims 42, 47, 52, 55, 67-72, 75, and 76 stand rejected under 35 USC § 103(a) as allegedly being unpatentable over U.S. Patent 419,942 to Harding ("Harding"). Applicant respectfully disagrees.

The sole rationale provided by the Office for the rejection of independent claim 11 as being obvious over Harding is that, allegedly, "it is well known in the art of nasal inhalers to plug a nostril not receiving treatment when using a nasal treatment requiring

only one nostril.”⁵ However, Applicant respectfully submits that amended claim 11 is patentable over Harding for the same reasons discussed in connection with the §103 rejection of claim 11 over Seidel.

The sole rationale for the rejection of independent claims 40 and 41 as being obvious over Harding is that, allegedly, it would have been obvious “to use the claimed range, since it has been held that where the general conditions of a claims [sic] are disclosed in the prior art, discovering the optimum workable range involves only routine skill.”⁶ However, this rationale fails to establish a *prima facie* case of obviousness because it too is a mere conclusory statement that lacks a clear rational underpinning supporting a legal conclusion of obviousness. It is unclear how this rationale relates to the claimed invention as a whole (e.g., it does do not address each element of the claimed combinations) or where the alleged “general conditions” of the claims are disclosed in the cited art.

Furthermore, Applicant notes that in the Office Action mailed December 27, 2007, Harding was cited in various rejections under 35 USC § 102(b) and 103(a).⁷ However, in the same Office Action, the Examiner stated that claims 11, 40, and 41 were allowable if rewritten in independent form.⁸ Applicants rewrote the claims in the subsequent Office Action, and the same claims are still pending in the present application as independent claims 11, 40, and 41. For all of the reasons already provided in the record, Applicant respectfully maintains that claims 11, 40 and 41 are allowable over Harding.

Applicant further submits that dependent claims 42, 47, 52, 55, 67-72, 75, and 76 are allowable as depending upon allowable base claims.

Keldmann and Chantrel

Claims 11, 14-17, 40-47, 52-55, 58, 61-63, 75 and 76 stand rejected under 35 USC § 103(a) as allegedly being unpatentable over WO 98/53869 to Keldmann et al

⁵ See the January 22, 2010 Office Action at page 4.

⁶ *Id.*

⁷ See December 27, 2007 Office Action at pages 2-4.

⁸ *Id.* at page 5.

(“Keldmann”) in view of FR 2,638,361 to Chantrel (“Chantrel”). In particular, the Examiner alleged that Keldmann teaches every claimed element except sealing one nostril, that Chantrel teaches using a common seal, and that it would have been obvious to modify Keldmann to use Chantrel’s seal “to prevent wasting and proper dispersion of medication.”

Applicant respectfully disagrees. The claimed invention, as a whole, would not have been obvious to one of ordinary skill in the art in view of the Examiner’s combination of Keldmann and Chantrel because the references do not teach or suggest all of the claimed elements and because the proposed combination would have required a fundamental change in the principle of operation of the base device.

The combination of Keldmann and Chantrel fail to teach or suggest every element of independent claims 11, 40, 41, and 45.

Applicant agrees with the Examiner that “Keldmann fails to specifically teach sealing one nostril.”⁹ Keldmann also fails to teach or suggest “delivering a gas flow entraining a substance through the outlet at such a driving pressure as to flow around the posterior margin of the nasal septum and out of the other nostril of the subject,” as required by independent claims 11, 40, 41, and 45. Chantrel fails to cure the deficiency of Keldmann because Chantrel, taken alone or in the proposed combination, fails to even hint at Applicant’s specifically claimed flow pattern.

With respect to claim 11, the Examiner also alleges that “it is well known in the art of nasal inhalers to plug a nostril not receiving treatment when using a nasal treatment requiring only one nostril.” This assertion was made ostensibly to establish that the recitation in claim 11 of “providing a flow resistance to the gas flow exiting the other nostril of the subject such as to maintain a dynamic positive pressure in the nasal airway of the subject” would have been obvious.¹⁰ However, Applicant respectfully submits that amended claim 11 is patentable over Keldmann and Chantrel for the same reasons discussed in connection with the §103 rejection of claim 11 over Seidel.

With respect to claims 40 and 41, the Examiner also alleges that it would have

⁹ January 22, 2010 Office Action at page 5.

¹⁰ *Id.*

been obvious “to use the claimed range, since it has been held that where the general conditions of a claims [sic] are disclosed in the prior art, discovering the optimum workable range involves only routine skill,” ostensibly to establish that the recited flow rates would have been obvious.¹¹ However, for the reasons provided above, the Examiner’s allegation is a mere restatement of a proposition of law and fails to establish how the prior art discloses the “general conditions” of the claims. One of ordinary skill in the art would not have understood the claim as a whole as being obvious because the cited art does not even hint at the specifically recited combination of sealed nostril, velum closure, flow pattern and flow rates.

One of ordinary skill in the art would not have combined Keldmann and Chantrel to produce the claimed invention because the combination would have required a change in the function of the base device.

When the Keldmann disclosure is read in its entirety, it is clear that the principal mode of operation of Keldmann’s device involves flow in one nostril followed by backflow out of the same nostril. Keldmann’s device is, in many portions of the specification, described as having a tubular nosepiece similar to a drinking straw. The specifically disclosed dimensions of Keldmann’s tubular nosepiece, and his stated preference for dimensions at the lower end of these ranges, is consistent with the principal mode of operation of the device involving flow in one nostril followed by backflow out of the same nostril. Additionally, the device of FIGS. 3 and 4 would not work for its intended purpose if the device were not a backflow device.

The Examiner proposes a modification of the Keldmann device that would incorporate a sealing nosepiece. If the Keldmann device were modified in this fashion, it would change the principle of operation of the device. With a sealing nosepiece, the Keldmann device would no longer operate on the principle of flow in one nostril followed by backflow out of the same nostril. Indeed, the principle of operation of a Keldmann-type device with the modification of a sealing nosepiece would be bi-directional flow – a concept that is nowhere described or even hinted at in Keldmann’s disclosure. Under the law, if the proposed modification would change the principle of operation of the prior art

¹¹ *Id.*

device, then the prior art teachings are not sufficient to render the claims *prima facie* obvious. *See In re Ratti*, 270 F.2d 810, 813, 123 USPQ 349, 352 (CCPA 1959).

For at least the foregoing reasons, Applicant respectfully submits that independent claims 11, 40, 41, and 45 are allowable over Keldmann and Chantrel. Furthermore, claims 14-17, 42-44, 46, 47, 52-55, 58, 61-63, 75 and 76 are allowable as depending upon allowable base claims.

Keldmann, Chantrel, and Side

Claims 48-51 stand rejected under 35 USC § 103(a) as allegedly being unpatentable over Keldmann in view of Chantrel as applied to claim 40 or 41, and further in view of U.S. Patent 3,888,252 to Side et al. (“Side”).

Claims 40 and 41 are patentable over Keldmann and Chantrel for at least the reasons discussed above. Side does not cure the deficiencies of Keldmann and Chantrel. Accordingly, claims 48-51 are patentable as depending upon allowable base claims.

Keldmann, Chantrel, and Butler

Claims 18, 56, and 57 stand rejected under 35 USC § 103(a) as allegedly being unpatentable over Keldmann in view of Chantrel as applied to claim 40, 41, and 45, and further in view of U.S. Patent 5,937,852 to Butler et al. (“Butler”).

Claims 40, 41, and 45 are patentable over Keldmann and Chantrel for at least the reasons discussed above. Butler does not cure the deficiencies of Keldmann and Chantrel. Accordingly, claims 18, 56, and 57 are patentable as depending upon allowable base claims.

Double Patenting

Claims 5-9, 11-18, and 40-46 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 252-281, 311, 350, and 389 of co-pending application U.S.S.N. 10/480,582. Applicant respectfully disagrees because the pending claims are patentably distinct and because the present application does not present an improper extension.

The Examiner alleged that the claims are not patentably distinct because “the

method steps set forth in the instant application are also claimed in the co-pending application.” This is factually incorrect. For example, none of the pending claims of U.S.S.N. 10/480,582 recite “delivering a gas flow entraining a substance through the outlet at such a driving pressure as to flow around the posterior margin of the nasal septum and out of the other nostril of the subject,” as required by independent claims 5, 9, 11, 40, 41, and 45. Numerous additional distinctions are clear upon comparison of the claims. For example, none of the pending claims of U.S.S.N. 10/480,582 recite “providing a flow resistance to the gas flow exiting the other nostril of the subject such as to maintain a dynamic positive pressure in the nasal airway of the subject,” as required by independent claim 11.

Furthermore, Applicant notes that the present application is a National Stage Entry of PCT/IB00/00273 filed 03/03/2000. U.S.S.N. 10/480,582 is a National Stage Entry of PCT/IB02/03034 filed 06/12/2002. Therefore, the present application is the earlier filed application and does not currently present the unjustified or improper time wise extension of the right to exclude.

Accordingly, Applicant respectfully requests that the double patenting rejections be reconsidered and withdrawn.

CONCLUSION

For the foregoing reasons, Applicant respectfully submits that all of the pending claims are in condition for allowance and requests early favorable action. If the Examiner believes a telephonic interview would expedite prosecution of this Application, the Examiner is welcome to contact Applicant's representatives at the numbers below.

Respectfully submitted,

Date: July 22, 2010

/Isaac A. Hubner, Reg. No. 61,393/
Isaac A. Hubner, Reg. No. 61,393
Agent for the Applicant
Proskauer Rose LLP
One International Place
Boston, MA 02110
Tel. No.: (617) 526-9893
ihubner@proskauer.com

/ Kristin H. Neuman, Reg. No. 35,530/
Kristin H. Neuman, Reg. No. 35,530
Attorney for the Applicant
Proskauer Rose LLP
1585 Broadway
New York, NY 10036-8299
Tel. No.: (212) 969-3385
kneuman@proskauer.com